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117TH CONGRESS
2D SESSION

H. R. 7253

To amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 28, 2022

Mr. PETERS (for himself, Mr. JOYCE of Pennsylvania, and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Clarifying Remanufacturing to Protect Patient Safety Act of 2022''.

SEC. 2. CLARIFICATION OF REMANUFACTURING IN DEFINITION.

Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(1) by subsection (a), by amending paragraph (1) to read as follows:

"(1) The term 'manufacture, preparation, propagation, compounding, or processing' shall include the following:

"(A) Repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

"(B) Remanufacturing of any finished device by engaging in any act that could significantly change the performance or safety specifications, or intended use, of the finished device, including by significantly changing—

"(i) a sterilization method;

"(ii) a reprocessing instruction;

"(iii) a control mechanism, operating principle, or energy input or output;

"(iv) the anatomical location of use; or

"(v) the design."; and

(2) in subsection (j), by adding at the end the following:

''(6) The Secretary shall require that lists of devices reported pursuant to paragraph (2) specifically identify in any such list those devices that have been or are being remanufactured as described in subsection (a)(1)(B).''.

SEC. 3. INSPECTION OF DEVICE REMANUFACTURING ESTABLISHMENTS.

Section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended—

(1) in paragraph (4)—

(A) by redesignating subparagraph (H) as subparagraph (G); and

(B) by inserting after subparagraph (F) the following:

''(G) Whether the establishment is registered as a remanufacturer or otherwise believed to be engaged in remanufacturing.''; and

(2) in paragraph (6)(A)—

(A) in clause (i), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and'' after the semicolon; and

(C) by adding at the end the following:

"(iii) the number of establishments registered as remanufacturers that the Secretary inspected in the previous calendar year;".

SEC. 4. DEVICE REMANUFACTURING PUBLIC EDUCATION.

(a) IN GENERAL.—The Secretary of Health and Human Services shall hold at least one public forum within 12 months after the date of enactment of this Act, and shall take other ongoing steps as necessary, to increase public awareness of the requirements applicable to device remanufacturing, including—

(1) holding webinars; and

(2) engaging in other outreach to regulated industry, professional societies, advocacy groups, State and local governmental entities, and other stakeholders.

(b) REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(A) prepare and post on the website of the Food and Drug Administration a report with regard to the remanufacturing of devices; and

(B) brief the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor,

and Pensions of the Senate regarding the findings of such report.

(2) CONTENTS.—The report under paragraph (1) shall include the following:

(A) A description of the activities carried out, and additional activities intended to be carried out, under subsection (a).

(B) The number of remanufacturing establishment registrations and remanufactured device listings under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), and any trends in such registrations and listings.

(C) An assessment of whether the Food and Drug Administration should issue guidance for remanufacturers on compliance with the establishment registration and device listing requirements of such section 510.

(D) A summary of inspections carried out, warning letters and other advisory actions, and enforcement actions relating to remanufacturing establishments since the date of enactment of this Act.

(E) The status of actions undertaken pursuant to the report issued by the Secretary pur-

suant to section 710 of the FDA Reauthorization Act of 2017 (Public Law 115–52).

(3) ANNUAL UPDATES.—On an annual basis, the Secretary of Health and Human Services shall—

(A) update the report required by this subsection with regard to the information described in subparagraphs (B) and (D) of paragraph (2); and

(B) post each such update on the website of the Food and Drug Administration.

(c) DEFINITION.—In this section and section 5, the term ''device'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

SEC. 5. ENHANCED COMMUNICATIONS REGARDING REMANUFACTURING.

The Secretary shall implement a process, to be posted on the website of the Food and Drug Administration, to receive through the Food and Drug Administration submissions from State regulatory bodies and other State authorities—

(1) expressing concerns that an entity that is remanufacturing devices—

(A) is not registered under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360); or

(B) may otherwise be acting contrary to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(2) describing any actions taken by State authorities against such entity.

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